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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,533	09/02/1997	PERTTI TORMALA	2880/27	9610

26646 7590 09/12/2003

KENYON & KENYON  
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NEW YORK, NY 10004

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/921,533

Applicant(s)

TORMALA ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-6 and 8-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt of request for extension of time and request for continued examination under 37 CFR 1.114 dated 8-25-03 is acknowledged.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-25-03 has been entered.

Claims 1-6 and 8-22 are pending.

Instant claim 1 recites a biodegradable and bioactive composite material comprising at least one resorbable polymeric matrix component, at least one reinforcing component and at least one bioceramic or bioglass reinforcing component mixed with matrix component, wherein the particle size of bioceramic or bioglass component is between 2 to 150 microns.

#### ***Claim Rejections - 35 USC § 112***

Claim 1 recites the limitation "particle size" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to applicants to amend the claim "wherein the bioceramic or bioglass reinforcing glass component has a particle size of".

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Claim 3 recites the limitation "resorbable polymeric reinforcing component" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "resorbable polymeric reinforcing component" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim, dependent from claim 2, recites "at least one fiber". However, claim 2 recites only one fiber and it is unclear from claim 3 as to which other fibers the claim is referring to.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-6 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,406,498 to Tormala et al (hereafter '498).

'498 teach bioactive biocomposite materials comprising a matrix of a bioabsorbable polymer, which is oriented and self-reinforced; and bioactive ceramic particles dispersed in the matrix (col. 3, lines 5-19). '498 teach same polymers (col. 4, lines 16-23 & examples) and bioactive glasses (col. 4, lines 35-58) as that of the instant claims. Further, '498 suggest using bioactive glass as fine particles or in the form of fibers having a size of 2 to 200 microns (col. 5,

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lines 5-16; figure 4 and example 1, col. 8, line 38-40). '498 teach the method of preparing the biocomposite material in col.5, lines 24-42. '498 further teach reinforcing the implants by addition of fibers manufactured of a resorbable polymer or a polymer alloy, other biodegradable glass or ceramic fibers (col. 6, lines 11-20). '498 teach preparing a composite by incorporating polymer, bioglass and reinforcing polymers; processing by melt extrusion or injection or compression molding (col. 6, lines 41-56 and col. 7, lines 12-19), all of which read on the claimed steps of preparing the instant composite material. '498 teach incorporating additive and biologically active substances in the composite material (col. 6, lines 25-40).

Instant claims recite a reinforcing polymer but does not state if the reinforcing polymer is same or different from the resorbable polymer. Accordingly, absent any distinction between components i) and ii) of the instant claim 1, the self-reinforcing polymer of '498 reads on both components i) and ii) of the instant claim. '498 teach that reinforcing the bioabsorbable polymer and bioglass particle composite transforms the non-reinforced composite materials into a strong, tough and partially porous form and further enhances new bone growth in close contact with the implant surface (example 4, col. 11-12). '498 do not state the diameter of the reinforced fibers of the instant claims. However, optimizing the diameter of the reinforcing fiber with an expectation to obtain strong implants that improve the bone growth and hence rapid healing and bone fixation would have been within the scope of a skilled artisan.

2. Claims 1-6 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,239,113 to Gross in view of Tormala et al (Proc. Instn. Engrs. 1998, submitted on PTO-1449).

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Gross teaches composition for the preparation of bone cement comprising an admixture methylmethacrylate copolymers and a bioactive glass ceramic powder having a particle size of 10 to 200 microns and vitreous mineral fibers (Example 1). Gross suggests that the mineral fibers also could be made of glass or bioactive glass ceramic composition (example 1). Gross does not teach a reinforcing polymer as claimed in the instant invention.

Tormala teaches bioabsorbable, biodegradable polymer composite for preparing bone fixation implants. The polymers taught by Tormala are the same as that claimed (table 10). Tormala teaches both non-reinforced and reinforced implants and suggests that polymer matrices reinforced with bioabsorbable fibers increase the strength, ductility and elastic modulus of the composite material (page 103). Further, Tormala suggests that the reinforcing fibers could be made of same polymer as that of the matrix. Instant claims recite a reinforcing polymer but does not state if the reinforcing polymer is same or different from the resorbable polymer.

Accordingly, absent any distinction between components i) and ii) of the instant claim 1, the self-reinforcing polymer of Tormala reads on both components i) and ii) of the instant claim. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare self reinforcing technique of Tormala to reinforce the polymer of Gross in the composition containing a polymer and a bioactive glass because Tormala teaches that the reinforced composite materials increase the strength of the bioabsorbable polymer by several fold making it stiff and strong. Further, optimizing the diameter of the reinforcing fiber with an expectation to obtain strong implants that improve the bone growth and hence rapid healing and bone fixation would have been within the scope of a skilled artisan.

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3. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 6,406,498 to Tormala et al (hereafter '498) as applied to claims 1-6 and 10-22 above, and further in view of Bonfield et al.

'498 discussed above do not teach the volume fraction of bioceramic as claimed in the instant invention. Bonfield et al teaches bone composites containing hydroxyapatite and polyethylene composites of 0.3-to 0.5 volume fraction, which imparts fracture toughness to the composite. Accordingly, it would have been obvious for one of a skilled artisan to prepare the bone composites of '498 having a volume fraction of 0.3 to 0.5 because Bonfield teaches that between the above volume fractions the composites possess increased toughness and strength of the composite and have comparable mechanical properties with that of the bone.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 and 8-22 have been considered but are moot in view of the new ground(s) of rejection.

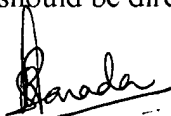


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
September 10, 2003